

EXHIBIT 2

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UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

University of Western Australia,
Junior Party
(Patent 8,486,907,
Inventors: Stephen Donald Wilton, Sue Fletcher and Graham McClorey),

v.

Academisch Ziekenhuis Leiden,
Senior Party
(Application 14/198,992,
Inventor: Judith Christina Theodora van Deutekom).

Patent Interference No. 106,013 (RES)
(Technology Center 1600)

Before: RICHARD E. SCHAFER, SALLY GARDNER LANE and
DEBORAH KATZ, *Administrative Patent Judges*.

SCHAFER, *Administrative Patent Judge*.

Decision - Priority - 37 CFR § 41.125(a)

I.

This interference is between Patent 8,486,907, assigned to the University of Western Australia (UWA), and Application 14/198,992, assigned to Academisch Ziekenhuis Leiden (AZL). UWA was put under an Order to Show Cause why judgment on priority should not be entered against it. Paper 193. Because UWA, has not satisfied its burden of establishing prima facie that it is has a basis that

1 would entitle it to a judgment on priority relative to senior party AZL, we enter
2 judgment on priority against UWA.

3 **II.**

4 The subject matter claimed by the parties is directed to methods for inducing
5 “exon skipping.” Exon skipping is a molecular biology technique that may be
6 useful for ameliorating or eliminating the effects of certain genetic mutations.
7 Those mutations may result in a shift in the reading frame during protein formation
8 resulting in a non-functional or partially functional protein. The exon skipping
9 technique, in effect, hides certain pre-mRNA exons from the mRNA formation
10 machinery. As a result, the hidden exon is removed along with introns during the
11 splicing that forms mRNA. Exon skipping is caused by binding an oligonucleotide
12 complementary to a particular pre-mRNA exon. The complimentary
13 oligonucleotide is referred to as an antisense oligonucleotide or “AON.” Both the
14 exon to be discarded and the AON are chosen to restore an open reading frame
15 allowing for the formation of a more complete and more functional protein.

16 Specifically, in the parties’ invention, the AON is selected to cause skipping
17 of exon 51 of the pre-mRNA associated with the gene that is responsible for the
18 formation of the protein dystrophin. The absence of dystrophin prevents skeletal
19 muscle development and causes the myopathies of muscular dystrophy. In those
20 suffering from Duchenne muscular dystrophy, the mutation in the dystrophin gene
21 essentially precludes the formation of functional dystrophin. By skipping, and thus
22 removing, exon 51 during the formation of mRNA, a reading frame is said to be
23 restored, resulting in the formation of a partially functional dystrophin protein.

24 The subject matter of this interference is defined by Count 1:

25 Claim 1 of [AZL] Application 14/198,992 or Claims 1, 19, 22
26 or 25 of [UWA] Patent 8,486,907.

27 Paper 1, p. 4.

UWA addresses its arguments to the count alternative of AZL's Claim 1. Thus, for the purpose of this opinion, it is only necessary to consider AZL's Claim 1. That claim provides:

1. A method for inducing the skipping of exon 51 of the human dystrophin pre-mRNA, said method comprising providing an oligonucleotide of 20 to 50 nucleotides in length to a cell, wherein said oligonucleotide is capable of binding to an exon-internal sequence of exon 51 of the human dystrophin pre-mRNA and inducing skipping of exon 51, wherein h51AONI (UCAAGGAAGAUGGCAUUUCU) (SEQ ID NO: 27) is capable of binding to said exon-internal sequence.

Paper 12, Clean Copy of Claims, 1:3-8.

Both parties were accorded the benefit dates of earlier applications. UWA's earliest effective filing date was that of its Australian Application AU 2004903474 filed June 28, 2004. AZL's earliest effective filing date was that of its PCT Application PCT/NL03/00214 filed March 21, 2003. Paper 1, Declaration, 5:10-23.

III.

A.

The subject matter of this interference relates to that involved in Interferences 106,007 and 106,008, also between UWA and AZL. During a telephone conference relating to the '007 and '008 Interferences, UWA requested authorization to file a motion for an additional interference between the patent and application involved here. Neither the '007 nor the '008 Interference involved the application and patent involved in this proceeding. AZL opposed declaring another interference arguing that if UWA wanted an interference it should have to file a reissue application and comply with the interference rules for suggesting an interference (i.e., 37 CFR § 41.202(a), (d) and (e)).

1 At the time of the conference call, AZL's involved '992 Application had
2 been allowed by the Examiner and was days away from issuing. This left
3 insufficient time to file a motion to declare an additional interference, an
4 opposition, and a reply. Because the claims of UWA's '907 Patent and AZL's
5 '992 Application appeared to be similar, this interference was declared in order to
6 withdraw the application from issue and avoid potentially issuing two patents to
7 the same invention. However, UWA as the junior party requesting an interference,
8 was required, and agreed, to file a motion establishing that an interference existed
9 between the claims of the '907 Patent and the '992 Application and to show that it
10 had a basis to prevail on priority. Paper 1, 2:18-21. The motion had to be
11 sufficient to establish that UWA would prevail on priority if AZL presented no
12 rebuttal argument or evidence. Paper 1, 3:7-8. In other words, UWA was required
13 to show, *prima facie*, that it had a basis to overcome the senior party's accorded
14 benefit date. These requirements paralleled the procedure an applicant must follow
15 in requesting an interference. *See* 37 CFR § 41.202(a), (d) and (e). Thus, UWA
16 entered this interference facing the same hurdles as a junior party applicant seeking
17 an interference.

18 UWA filed its motion. Paper 133. AZL opposed. Paper 148. UWA filed a
19 reply. Paper 152.

20 **B.**

21 UWA's motion (Paper 133) argued that an interference exists between the
22 parties' claims and that all of its claims correspond to the count. Paper 133, 4:1 –
23 6:12. As to prevailing on priority, UWA argued that AZL's involved claims lack
24 both a written description and an enabling disclosure sufficient to support the
25 breadth of those claims in AZL's involved and parent applications. Paper 133,
26 11:20 – 14:9. Specifically, with respect to written description, UWA argued that
27 the breadth of AZL's claims was not supported:

AZL's claims are directed to the nascent and highly unpredictable technology of exon skipping AONs intended for therapeutic use. These claims are exceedingly broad, encompassing hundreds of billions, trillions, or incalculable numbers of potential compounds, and rely on functional language to define the claimed genera.

Paper 133, 12:7-10. According to UWA, AZL's single disclosed species of an AON was insufficient to provide a written description of the genus of AON's specified in the claims:

Despite this breadth and the unpredictability, the AZL applications disclose just a single species of AON allegedly capable of inducing *in vitro* skipping of exon 51, and identifies no structural features common to the members of the genus.

Paper 133, 12: 10-12. With respect to enablement, UWA maintained that AZL's specification failed to "enable a person of ordinary skill in the art to make and use the full scope of the claimed invention without undue experimentation." Paper 133, 12:22-24. UWA argued:

The various claims of the '992 application cover hundreds of billions, trillions, or incalculable numbers of AONs with significant chemical variability, but the applications disclose just a single AON capable of inducing *in vitro* skipping for exon 51. Exon skipping is extremely unpredictable: changes to the nucleobase sequence, chemical backbone, and internucleotide linkages of the AON all influence the ability of the AON to induce exon skipping. The quantity of experimentation required to determine which AONs are capable of inducing exon 51 skipping *in vitro* is undue.

Paper 133, 13:13-19. UWA further argued that the records of the involved and parent application do not include clinical data or provide evidence of *in vivo* activity. Paper 133, 13:21 – 14:2. As a result, UWA argued: "[t]he quantity of experimentation needed to use the full scope of AZL's claimed invention to treat patients is staggering." Paper 133, 14:2-3.

1 **C.**

2 AZL's Opposition (Paper 148) did not contest that an interference exists
3 between the parties' claimed subject matter or challenge the designated claim
4 correspondence specified in the Notice of Declaration (Paper 1). AZL argued,
5 *inter alia*, that UWA failed to establish that UWA has a basis on which it could
6 prevail on priority. Specifically, AZL argues that UWA did not allege a date of
7 invention earlier than AZL's accorded benefit dates and did not show that AZL is
8 not entitled to those dates. Paper 148, 3:14 – 4:15.

9 **D.**

10 A panel of the Board held that UWA had not established a prima facie basis
11 upon which it could prevail on priority. Paper 192, 11:19-23. As a result, UWA
12 was put under an order to show cause why judgment on priority should not be
13 entered against it. Paper 193.

14 **IV.**

15 In its response to the Order to Show Cause, UWA presents four reasons it
16 feels justify continuing this interference: (1) UWA's showing of unpatentability of
17 AZL's claims is sufficient to establish priority; (2) this interference should be
18 suspended and the outcome should be contingent on the outcome of Interference
19 106,008; (3) AZL's involved claims are unpatentable under 35 U.S.C. § 135(b)(1);
20 and (4) AZL's involved claims are unpatentable under 35 U.S.C. § 112, ¶ 1.

21 **A.**

22 UWA argues "unpatentability is an appropriate basis to establish priority"
23 over a senior party. Paper 194, 4:8 – 6:16. UWA directs us to MPEP, 6th Ed.,
24 Rev. 3, dated July 1997, ¶ 2308.02 (Ex. 2143) and three interference opinions for
25 support of its position. Paper 194, 4:8 – 6:16.

1 **1.**

2 The cited portion of the MPEP provided guidance in the application of 37
3 CFR § 1.608(b). The cited MPEP paragraph and § 1.608(b) have been superseded
4 and have no relevance to this interference.

5 The referenced rule, 37 CFR § 1.608(b), required that the junior party
6 present evidence that would *prima facie* entitle it to a “judgment” relative to the
7 senior party. Thus the rule required that the junior party

8 file evidence which may consist of patents or printed
9 publications, other documents, and one or more affidavits
10 which demonstrate that applicant is *prima facie* entitled to a
11 *judgment* relative to the patentee and an explanation stating
12 with particularity the basis upon which the applicant is *prima*
13 *facie* entitled to the *judgment*.

14 37 CFR § 1.608(b) (emphasis added). The rule also required specific showings
15 where the basis for a judgment was priority:

16 Where the basis upon which an applicant is entitled to judgment
17 relative to a patentee is priority of invention, the evidence shall
18 include affidavits by the applicant, if possible, and one or more
19 corroborating witnesses, supported by documentary evidence, if
20 available, each setting out a factual description of acts and
21 circumstances performed or observed by the affiant, which
22 collectively would *prima facie* entitle the applicant to judgment
23 on priority with respect to the effective filing date of the patent.

24 *Id.*

25 The cited portion of the MPEP explained the showings required § 1.608(b):

26 The showing under 37 CFR 1.608(b) must be such as to show
27 that the applicant is *prima facie* entitled to a *judgment* relative
28 to the patentee. Since 35 U.S.C. 135(a), as amended by Public
29 Law 98-622, now gives the Board jurisdiction in an interference
30 proceeding over questions of both priority and patentability, the
31 37 CFR 1.608(b) showing need not attempt to show prior
32 invention by the applicant, but may instead demonstrate that the
33 applicant would be entitled to a *judgment* against the patentee

1 on a ground of unpatentability (as, for example, that the claims
2 of the patent which will correspond to the count or counts are
3 unpatentable over prior art or prior public use, or that the patent
4 does not comply with 35 U.S.C.112).

5 Ex. 2143 (emphasis added). Thus, the rule at least implicitly, if not expressly, and
6 consistent with MPEP ¶ 2308.02 (Ex. 2143), permitted demonstrating entitlement
7 to *judgment* by showing unpatentability in addition to priority.

8 The interference rules, however, were rewritten in 2004. Section 1.608(b)
9 was replaced with § 41.202. Unlike § 1.608(b), § 41.202(d) specifically requires
10 that the junior party show a prima facie basis for prevailing on priority, rather than
11 prima facie entitlement to a judgment:

12 (d) *Requirement to show priority under 35 U.S.C. 102(g).* (1)
13 When an applicant has an earliest constructive reduction to
14 practice that is later than the apparent earliest constructive
15 reduction to practice for a patent or published application
16 claiming interfering subject matter, the applicant must show
17 why it would prevail on *priority*.

18 37 CFR § 41.202(d) (emphasis added). Section 41.202(d) specifically requires that
19 priority be shown pursuant to 35 U.S.C. § 102(g). That section provides in
20 relevant part:

21 A person shall be entitled to a patent unless -

22 *****

23 (g)(1) during the course of an interference conducted under
24 section 135 . . . , another inventor involved therein establishes,
25 to the extent permitted in section 104, that before such person's
26 invention thereof the invention was made by such other
27 inventor and not abandoned, suppressed, or concealed it

28 In determining priority of invention under this subsection, there
29 shall be considered not only the respective dates of conception
30 and reduction to practice of the invention, but also the
31 reasonable diligence of one who was first to conceive and last
32 to reduce to practice, from a time prior to conception by the
33 other.

1 35 U.S.C. § 102(g).

2 The MPEP has also been revised and, like § 41.202(d), requires a showing
3 of priority:

4 Whenever the application has an earliest constructive reduction-
5 to-practice that is later than the earliest constructive reduction-
6 to-practice of a published application having allowed claims or
7 a patent with which it interferes, the applicant must make a
8 priority showing under 37 CFR 41.202(d)(1).

9 MPEP, 9th Ed. (March 2014), ¶ 2305.¹

10 Thus, under the current procedures, a junior party requesting an interference
11 must show that it is entitled to priority. That showing must be sufficient to
12 support, if unrebutted by the opponent, a determination of priority in favor of the
13 party making the showing. 37 CFR § 41.202(e)(1). Merely showing that the
14 opponent's claims are unpatentable is not enough.

15 **2.**

16 UWA asserts that AZL's claims lack both a written description and an
17 enabling disclosure sufficient to support the breadth of its involved claims. Those
18 claims, it is argued' are therefore unpatentable under 35 U.S.C. § 112, first
19 paragraph, entitling AZL to a judgment of priority. Under the facts here, we do not
20 agree.

21 **a.**

22 As a condition for continuing this interference, UWA was under the burden
23 of establishing priority over AZL's accorded benefit dates. Priority in an
24 interference is determined on the basis of one or more counts. When an
25 interference is declared, the count or counts are identified and a preliminary
26 determination of priority is made based upon the accorded benefit dates for each

¹ This interference was declared September, 29, 2014, after the effective date of the MPEP.

1 count. A party is accorded the benefit of the filing date of applications that are
2 proper constructive reductions to practice under 35 U.S.C. § 102(g)(1); 37 CFR
3 § 41.201, definition of “benefit.” An application is a constructive reduction to
4 practice if it includes a described and enabled anticipation under § 102(g)(1) of the
5 subject matter of the count. *Id.*, definition of “constructive reduction to practice.”
6 The parties are presumed to have invented the interfering subject matter in the
7 order of their accorded benefit dates. 37 CFR § 41.207(a)(1). The senior party is
8 the inventor presumed under § 41.207(a)(1) to be the first inventor. 37 CFR §
9 41.201, definition of “senior party.” The senior party’s benefit date is important
10 because it is the date the junior party must overcome in showing priority.

11 Overcoming an opponent’s benefit date may be accomplished by showing
12 the incorrectness of an accorded benefit date (i.e., the date of a constructive
13 reduction to practice). Thus, a junior party may seek the benefit of the filing dates
14 of additional applications and/or attack the senior party’s accorded benefit dates.
15 A junior party may also show priority by establishing priority on the merits (i.e.,
16 actual reduction to practice or conception and diligence).

17 Priority based on a constructive and actual reduction to practice involve
18 similar concepts. Proof of an actual reduction to practice of a species or
19 embodiment within the scope of the count prior to the opponent’s date results in an
20 award of priority against the opponent. *Medichem S.A. v. Rolabo S.L.*, 437 F.3d
21 1157, 1169 (Fed. Cir. 2006). Similarly, a benefit application need only describe a
22 single enabled species or embodiment within the scope of the count to constitute a
23 constructive reduction to practice. *Hunt v. Treppschuh*, 523 F.2d 1386, 1389
24 (CCPA 1975) (For the purpose of priority in an interference, where an “application
25 is relied upon as a prior constructive reduction to practice[,] . . . the § 112, first
26 paragraph requirements need only be met for an *embodiment* within the count.”)
27 *See also, Falkner v. Inglis*, 448 F.3d 1357, 1362 (Fed. Cir. 2006).

b.

UWA's attack on the breadth of AZL's claims does not, under the facts here, establish priority with respect to AZL's accorded benefit. AZL is entitled to those dates as long as its involved and benefit applications describe an enabled embodiment meeting all the limitations of the count. *Hunt, supra; Falkner, supra.* In order to defeat AZL's accorded benefit dates and show a basis for priority, UWA must establish that AZL's involved and benefit applications do not describe an enabled embodiment meeting the limitations of the count.

UWA has not made that showing. Example 1 of AZL's involved application and each of its benefit applications appear to be identical. Example 1 facially appears to describe all the limitations, and thus "anticipates," the Count alternative of AZL's Claim 1. See Paper 133, 12:10-12. See 37 CFR § 41.201, definition of "constructive reduction to practice." UWA has not asserted that Example 1 in AZL's involved application or AZL's benefit applications does not describe an enabled embodiment meeting all the limitations of AZL's Claim 1 and, therefore, the limitations of the Count. Thus, UWA has not established that AZL is not entitled to the benefit of the dates of its involved and earlier applications, including the March 21, 2003, filing date of its International Application PCT/NL2003/000214. Under these circumstances, UWA's scope argument is insufficient to establish, *prima facie*, priority over AZL's accorded benefit dates.

B.

Referring to our Decision on Motions (Paper 192 at 7:20-25) UWA argues that

the Board Decision [improperly] assumes the Count in the '013 interference is appropriate to define the interfering subject matter between the parties. It is not, however, because as UWA has explained in the '008 interference, the subject matter defined by the Count is unpatentable to AZL.

1 Paper 194, 8:23 – 9:1

2 UWA, however, has not requested authorization to file a motion to substitute
3 a more appropriate count for establishing its case for priority. Nor has it sought
4 authorization to file a motion attacking the benefit accorded AZL. *Cf.* 37 CFR §
5 41.202(d)(2), last sentence.

6 C.

7 UWA refers us to three interference opinions said to support its argument
8 that a showing of unpatentability under § 112, ¶ 1, should be sufficient to prove
9 priority. In each case, like UWA here, the junior party did not assert a date of
10 invention earlier than its opponent's filing date but presented a challenge to the
11 patentability of the senior party's claims under § 112, ¶ 1. Thus, in *Gould v.*
12 *Hellwarth*, 472 F.2d 1383 (CCPA 1973), the invention was an improved laser. *Id.*
13 at 1384. The junior party Hellwarth asserted that senior party Gould's disclosure
14 did not enable how to make any type of a laser. The CCPA agreed and concluded
15 that Gould's disclosure did not enable how to make a laser. It affirmed the award
16 of priority to Hellwarth.

17 In *Brown v. Fodor*, Interference 104,358 (B.P.A.I 1999) (Ex. 2113), Junior
18 Party Brown attacked the filing date of Fodor's patent asserting Fodor's disclosure
19 did not adequately describe or enable the interfering subject matter. Ex. 2113, p. 2.
20 The Board held that Brown failed to establish that Fodor's specification did not
21 satisfy the written description and enablement requirements. Ex. 2113, pp. 6 and
22 11. Because Brown did not establish that Fodor's involved claims lacked
23 descriptive or enabling support, judgment on priority was awarded against Brown,
24 based on Fordor's earlier accorded benefit date.

25 In *Tanabe v. Lee*, 2004 W.L. 3217733 (B.P.A.I 2004), the Junior Party
26 Tanabe was authorized to file a motion asserting that Lee's copied claims did not
27 have written descriptive support in Lee's disclosure. The Board granted Tanabe's

1 motion holding that Lee's specification failed to provide written descriptive
2 support for the involved claims. The Board entered judgment against the Senior
3 Party. 2004 W.L. 3217733, *5.

4 While those cases support the proposition that a showing that claims are
5 unpatentable under § 112, ¶ 1, may be sufficient to disprove the senior party's
6 priority, those cases do not involve the scope argument raised here by UWA. In
7 each case it was asserted that certain claim limitations had no § 112 support, not
8 just that those limitations encompassed more than what was supported by the
9 disclosure. When § 112 support is totally lacking, the senior party's application
10 simply is not a constructive reduction to practice of the involved subject matter.
11 The filing date of the application is not a constructive date of invention. In effect,
12 as to unsupported subject matter, the senior party has no date of invention. By
13 showing that the senior party has no support, the junior party has established
14 "priority" by virtue of its own constructive reduction to practice and filing date.

15 On the other hand, a junior party's showing that the senior party's claims are
16 broader than permitted by the senior party's disclosure is not sufficient to deprive
17 the senior party of a constructive reduction to practice and an effective filing date
18 where that disclosure describes an enabled embodiment meeting all the count
19 limitations. An application disclosure is a constructive reduction to practice of
20 everything adequately disclosed therein. *See Renz v. Jacob*, 326 F.2d 792, 796
21 (CCPA 1964). *See also Hyatt v. Boone*, 146 F.3d 1348, 1352 (Fed. Cir. 1998)
22 (The filing of a patent application serves as conception and constructive reduction
23 to practice of the subject matter described in the application). "For the purpose of
24 priority in an interference, where an "application is relied upon as a prior
25 constructive reduction to practice[,] . . . the § 112, first paragraph requirements
26 need only be met for an *embodiment* within the count Section 112, first paragraph."
27 *Hunt*, 523 F.2d at 1389; *Falkners*, 448 F.3d at 1362. An earlier described and

1 enabled embodiment remains a constructive reduction to practice of the invention.
2 That described and enabled embodiment is sufficient to defeat the junior party's
3 claim of priority as to the subject matter of the count, notwithstanding the alleged
4 unpatentability of the senior party's claims for undue breadth.

5 UWA has not shown that AZL's involved and parent applications do not
6 describe an enabled embodiment meeting the limitations of the count. As we noted
7 above, Example 1 in AZL's involved and benefit applications, appears to meet the
8 the limitations of the count alternative of AZL's claim 1. See Paper 133, 12:10-12.
9 On this record, AZL has not been shown to lack entitlement to its accorded benefit
10 dates. UWA has failed to show, *prima facie*, priority as to the subject matter of the
11 count.

12 **D.**

13 Each of UWA's remaining arguments for continuing this interference
14 revolve around the alleged unpatentability of AZL's claims. Thus, UWA argues
15 that AZL's claims are unpatentable under 35 U.S.C. §§ 135(b)(1) and 112, ¶ 1.
16 Paper 194, 11:16 – 14:13. UWA also argues that AZL's involved claims included
17 the same unpatentable limitations as AZL's claims under attack in the '008
18 interference. Paper 194, 6:20 – 11:15.

19 We are not persuaded by these arguments.

20 This interference was requested by UWA. Paper 1, 2:3-5. Because UWA
21 was the apparent junior party, and notwithstanding that it was a patentee, it was
22 required, and it agreed, to file a motion to establish, *inter alia*, why it would prevail
23 on priority:

24 [S]ince the circumstances for declaring this interference
25 are somewhat unusual, UWA is required, and agreed, to file a
26 motion to establish that an interference exists and show that it
27 has a basis to prevail on priority. Cf. 37 C.F.R. § 41.202(a)
28 and (e).

1 UWA shall file a motion to establish that an interference
2 exists between its '907 patent and AZL's '992 application.
3 The motion shall include the following:

4 (1) a claim chart comparing at least one claim of each
5 party corresponding to the count and show why the claims
6 interfere within the meaning of §41.203(a);

7 (2) Explain in detail why UWA will prevail on priority;
8 and

9 (3) for each application for which benefit has been
10 accorded, provide a chart showing where the disclosure
11 provides a constructive reduction to practice within the scope
12 of the count.

13 UWA's motion must establish that it would, if
14 un rebutted, support a determination of priority in favor of
15 UWA.

16 Paper 1, 2:16 – 3:5.

17 Pre-AIA 35 U.S.C. § 135(a) authorizes the director to address the issue of
18 multiple claimants for the same patentable invention by declaring an interference
19 to determine which of those claimants was the first inventor. Although issues of
20 patentability may be considered, the purpose of an interference proceeding is to
21 determine priority of invention—to decide who among multiple patent applicants
22 (or applicants and patentees) was the first to invent claimed subject matter.
23 *Minnesota Min. & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 674 (Fed. Cir. 1991).
24 The emphasis on priority is manifest in § 135(a) (emphasis added): “[T]he [Patent
25 Trial and Appeal Board] *shall* determine questions of priority of the inventions and
26 *may* determine questions of patentability.”

27 Whether the Director initiates or continues an interference is discretionary.
28 “The plain meaning of this statute [35 U.S.C. § 135(a)] is clear from the use of the
29 permissive term ‘may’ that the [Director] has discretion whether to declare an
30 interference.” *Barton v. Adang*, 162 F.3d 1140, 1144 (Fed. Cir. 1998).

31 Section 135(a) states that the Board shall determine questions
32 of priority once an interference proceeding is declared. This

1 authority for the Board to determine questions of priority,
2 however, does not vitiate the Director's discretion to begin or
3 discontinue an interference once declared.

4 *Eli Lilly & Co. v. Board of Regents of the University of Washington*, 334 F.3d
5 1264, 1267 (Fed. Cir. 2003). The Director's discretion in interferences has been
6 delegated to the Board. 37 CFR § 41.203(b).

7 Long established PTO practice requires a junior party requesting an
8 interference to present a basis on which it could prevail on priority before allowing
9 an interference to proceed. *E.g.*, *Ewing v. United States ex rel. The Fowler Car*
10 *Company*, 244 U.S. 1 (1917) (Upholding the Commissioner of Patents' authority to
11 decline proceeding with an interference where the junior party did not present
12 circumstances showing a date of invention prior to the filing date of the opponent);
13 *Kistler v. Weber*, 412 F.2d 280, 283-85 (CCPA 1969); *Edwards v. Strazzabosco*,
14 2001 WL 697944, (Bd. Pat. App. & Inter. 2001). *See also*, 37 CFR § 41.202(a)(4).
15 An interference is not simply a pre-grant opposition or a post-grant cancellation
16 proceeding. It is not simply a vehicle for a junior party to challenge the
17 patentability of a senior party's claims. It is fundamentally, and at center, a
18 priority contest to determine between two or more parties who was the first to
19 invent the interfering subject matter. UWA apparently seeks an interference, not to
20 establish that it was the first to invent, but to show that AZL's claims are
21 unpatentable. We decline to exercise discretion to allow a junior party who has not
22 established a colorable basis for priority to challenge the patentability of the senior
23 party's claims.

24 As things now stand in this interference, UWA's involved claims are
25 unpatentable under 35 U.S.C. § 102(g)(1) over AZL's subject matter. UWA was
26 given the opportunity and attempted to provide a basis upon which it could prevail
27 on priority. It was not successful in that attempt. Without UWA providing a

1 colorable basis to prevail on priority, its unpatentability assertions alone provide an
2 insufficient basis to continue this interference. We therefore exercise our
3 discretion to discontinue this interference with a judgment against the junior party
4 UWA. In this regard, we note that, in the event AZL's involved application issues,
5 UWA may raise many, if not all, of its challenges by means of a Post Grant
6 Review under 35 U.S.C. § 321.

7 **V.**

8 UWA has failed to satisfy its burden of showing prima facie entitlement to a
9 judgment of priority. UWA has failed to show cause why judgment should not be
10 entered against it. A judgment will be issued against UWA in a separate paper.

11

cc (via email):

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